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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,118	07/02/2003	Darlene M. Dreon	0125-UTL	3886

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/612,118	Applicant(s) DREON ET AL.	
	Examiner Shirley V. Gembeh	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-74 are pending.

Claims 1-74 are rejected.

Response to Arguments

In response to the office action dated September 19, 2005, Applicant has provided arguments for the patentability of claims 1-74.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Claim Rejections - 35 USC § 103

Claims 1-74 remain rejected under 35 USC § 103 (a) as being patentable over Beinlich, et al., US 2005/00124689, Kapoor et al., US 2002/0068100, Bland et al., US 2002/0192310, Miller et al., US 6,426,362, Seikie et al., US 2003/0086981, Horrobin US 6,479,544 and 5,120,760. The rejection is maintained for the reason of record set forth in the prior office action.

Applicants' argument filed December 16, 2005 have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

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references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the cited prior art: Beinlich, et al., US 2005/00124689, Kapoor et al., US 2002/0068100, Bland et al., US 2002/0192310, Miller et al., US 6,426,362, Seikie et al., US 2003/0086981, Horrobin US 6,479,544 and 5,120,760 are to a composition/method for treating conditions associated with PMS.

On page 12 of Applicants' argument

Applicants note that in the rejection of Claims 1-45, the Examiner has relied upon the combination of six references. In the rejection of Claims 46-74, the Examiner has relied upon the combination of five references. The Office Action goes into detail about the teachings of each reference; however, the action fails to provide the *motivation* to combine all of the references. The Office Action states that:

[t]he Beinlich references teaches one skilled in the art at the time of the invention was made would have obtained the same result as claimed by combining together the teachings taught be Kapoor, Bland, Miller, Seiki, and Horrobin to treat PMS or PMDD related symptoms. One of ordinary skill in the art would have known that administering to a female a non-alpha tocopherol or metabolite thereof with an omega-3 poly-unsaturated fatty acid would reduce the symptoms of PMS or inflammation.

The Office Action, pages 4-5. This argument relies on what one of skill in the art would have known rather than whether they would have combined the references teachings to arrive at the claimed invention. This is insufficient to establish a *prima facie* case of obviousness over claims 1-45 because it relies on level of skill in the art. See MPEP §2143.01.

The motivation to combine the above cited reference lies in the treatment of PMS, and as clearly stated by applicant that there must be some suggestion in the reference or in the knowledge generally available to the ordinary skill in the art to modify

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or combine. In this case it is well known in the art that tocopherols (vitamin E) and omega-3 have been used in the treatment of PMS or PMS related diseases. It is well within one of ordinary skill in the art to combine the teachings of the prior art because they all teach treating PMS and using the various teachings to modify the composition is motive enough to combine the art, as the end analysis is to treat conditions of PMS.

The instant invention differs from the primary prior art in that it did not recite omega-3-poly-unsaturated fatty acid, however indicated test for levels of unsaturated fatty acid in the blood e.g. linoleate, which is an n-3. The skilled artisan would have been motivated to add omega-3-poly-unsaturated fatty acid to the composition to treat PMS symptoms in patients with low levels of fatty acid in their blood because these compounds are known to the skilled artisan to regulate pain and maintain cell function. Further, (see § 0124 Beinlich et al) indicates that the composition can further comprise of other ingredients. "Or other ingredients" interpreted here to be anything that will aid the patient in feeling better, a motive enough to combine.

Next, an argument stating there is no motive is not sufficient, since the skilled artisan would have known --a knowledge generally available to the one of ordinary skill, therefore would have combined the above cited references at the time the claimed invention was made and arrived at the same invention.

With regards to the kit claims 46-74:

In addition, the printed matter on a label or package insert of a kit or container does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package

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insert of a kit and the product, composition, or article of manufacture of a kit or container.

See *In re Haller* 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of *In re Haller*, it is stated that: Whether the statement of intended use appears merely in the claim or in label on the product is immaterial so far as the question of Patentability is concerned . . . In accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

Also see *In re Venezia* 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, *In re Miller* 164 USPQ 46 (CCPA 1969) and *In re Gulak* (CAFC) 217 USPQ 401 relate to a mathematical device and to a measuring cup respectively as well as *In re Ngai*, 70 USPQ2d 1862 (CAFC 2004). In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself, which is a patentable distinction because the function of the device depends upon the printed matter itself, which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function.

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Such is not the case with the instantly claimed articles or kits. The claimed articles of the kit remain fully functional absent the labeling or printed instructions for use.

Thus the instructions for use included in a kit or article manufacture constitute an "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

In the instant case, the kit claims are drawn to an old article or composition, which further comprises labeling instructions. The intended use, which is recited on the label or package of the insert, lacks a function relationship because the insert or label does not physically or chemically affect the chemical nature within the article of manufacture, and furthermore, the skilled artisan can still use the old article or old composition of the kit for other purposes. Therefore the old article or composition which are comprised with the claimed kit are unpatentable over the prior art, because they function equally effectively with or without the labeling, and accordingly no functional relationship exists between the instructions for use and the composition.

Thus the claims are addressed as being drawn to an article of manufacture comprising an old composition of a kit and a package insert, the instructions on the insert bearing no patentable weight with regard to double patenting, 102 and 103 rejections.

Applicants' argument has been fully considered but found unpersuasive and the rejection in the prior office action is hereby maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

I. Claims 1-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42 of copending Application No. 10/295,493. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Both sets of claims refer to treating inflammation – premenstrual syndrome (PMS) in the current application (claims 1 - 50) and muscle inflammation (claim 42) in the copending application. The current application claims anticipate the copending application claims

Both applications recite using the same compositions and/or derivatives thereof. See current application claims 1 – 50 and copending application claim 42. The compositions recited in the claims are anticipatory of each other.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

II. Claims 1-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-11, 37-43 of

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copending Application No. 10/227,094. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Both sets of claims refer to treating inflammation – premenstrual syndrome (PMS) in the current application (claims 1 - 50) and C-reactive associated inflammation (claim 1, 3-11,37-43) in the copending application. The current application claims anticipate the copending application claims

Both applications recite using the same compositions and/or derivatives thereof. See current application claims 1 – 50 and copending application claims 1, 3-11,37-43. The compositions recited in the claims are anticipatory of each other.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

III. Claims 1-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 6, 9, 12-43 of copending Application No. 11/038,373. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Both sets of claims refer to treating inflammation – premenstrual syndrome (PMS) in the current application (claims 1 - 50) and C-reactive protein associated inflammation (claim 1, 3, 6, 9, 12-43) in the copending application. The current application claims anticipate the copending application claims

Both applications recite using the same compositions and/or derivatives thereof. See current application claims 1 – 50 and copending application claims 1, 3, 6, 9, 12-43. The compositions recited in the claims are anticipatory of each other.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

IV. Claims 1-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-75 of

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copending Application No. 10/967,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Both sets of claims refer to treating inflammation – premenstrual syndrome (PMS) in the current application (claims 1 - 50) and C-reactive protein associated inflammation (claims 1-75) in the copending application. The current application claims anticipate the copending application claims

Both applications recite using the same compositions and/or derivatives thereof. See current application claims 1 – 50 and copending application claims 1-75. The compositions recited in the claims are anticipatory of each other.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

The above double patenting rejections all have overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembah whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
2/15/06


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